



County of Erie

MARK C. POLONCARZ
COUNTY EXECUTIVE

DEPARTMENT OF HEALTH

Gale Burstein, M.D., M.P.H.
Commissioner of Health

TO: All E.M.S. Providers

FROM: John Adolf, Deputy Commissioner / E.M.S.
Erie County Division of Emergency Medical Services

DATE: March 7, 2012

SUBJECT: Cardiac Science Automated External Defibrillator (AED) Recall

Cardiac Science is conducting a voluntary recall of a limited number of automated external defibrillators (AEDs) manufactured between July 1, 2011 and December 30, 2011. The affected AEDs contain a circuit board manufactured with a component that may fail unexpectedly due to a supplier manufacturing defect. If the component were to fail during a rescue attempt, the AED may not deliver defibrillation therapy.

This issue was detected at the Cardiac Science factory through our standard quality control processes. We have no reports of this issue impacting a rescue. This action is being conducted with the knowledge of the appropriate Regulatory Agencies.

Each affected AED should be returned to Cardiac Science for correction as soon as possible.

Cardiac Science is contacting affected customers to facilitate the return of the AEDs to the factory. All affected AEDs will be corrected at no charge to the customer.

Customer can contact Cardiac Science at 1.888.402.2484 (in the United States). Outside the United States, customers can contact us at +1.425.402.2482 or speak with the local Cardiac Science representative. Customers can also email Cardiac Science at aed210@cardiacscience.com for more information.

Models Affected:

Powerheart 9300A, 9300E, 9300P, 9390A, 9390E, CardioVive 92532, 92533, CardioLife 9200G, 9231, and the GE Responder and Responder Pro.

Serial Number Search

To determine if a device is affected by this voluntary medical device correction, you may enter the serial number of a unit in question on the Cardiac Science website at <http://www.cardiacscience.com/services-support/service-announcements-and-upgrades/aed210.php?> to determine if a particular unit is affected by the recall.

If you should have any questions, please contact us at the E.M.S. office at 681-6070.

Cc Commissioner Burstein
Commissioner Neaverth